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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,447	04/22/2005	Aldo Pinchera	B-0496 PUS	1713

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EXAMINER	
ZHANG, NANCY L	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/532,447	PINCHERA ET AL.	
	Examiner	Art Unit	
	Nancy L. Zhang	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending and examined.

Specification

The disclosure is objected to because of the following informalities: the word "unexpectedly" being used in the specification in numerous places is misspelled as "unespectedly". Examples of such misspelling can be found at page 2, line 23 and page 5, line 15 and 23.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5, 9, 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 5 recite the limitation "the treatment" in claim 2. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 9, the phrase "like" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 15 recites the limitation "the differential or sequential administration" in any one of claims 8 or 11 to 14. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "the preparation" in any one of claims 1, 8 or 10 to 14. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 provides for the use of triiodothyronine sulfate for the preparation of pharmaceutical compositions, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. For examination purposes, claim 16 is interpreted as "a method of using Triiodothyronine Sulfate in a medicament".

Claim 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lopresti et al. ("Characteristics of 3;5,3'-Triiodothyronine Sulfate Metabolism in Euthyroid Man", Journal of Clinical Endocrinology and Metabolism, Vol. 73, No. 4, 1992, pages 703-709, item "CA" on PTO 1449 filed on 02/14/2006).

Claims 1-7 and 9 are directed to a pharmaceutical composition comprising the compound triiodothyronine sulfate (T_3S). Claim 9 limits that the composition further comprises additives like excipients, diluents, dissolvents, solvents, carriers, dyestuffs, flavourings, sweeteners. Claim 16 is directed to a method of using triiodothyronine sulfate in a medicament.

Lopresti et al. disclose that 25 μCi of 3,5,3'-Triiodothyronine Sulfate (T_3S) in a 5% human albumin solution was administered to human volunteers (page 704, left column, last paragraph).

Therefore, a pharmaceutical composition comprising triiodothyronine sulfate (T_3S) and a method of using triiodothyronine sulfate in a medicament are clearly known in the art.

Claim 9 recites a limitation that the composition further comprises additives such as a solvent. Lopresti et al. disclose that 25 μCi T_3S mixed in 20 mL human albumin solution in distilled water was orally administered (page 704, right column, 4th paragraph).

The recitation of "for use as a medicament" in claims 1 and 2, the recitation of "for use in the treatment of pathologies due to organic deficiency of triiodothyronine" in claim 3, the recitation of "said pathologies comprise original hypothyroidism from

autoimmune thyroid affections, hormonal production defects, thyroidectomy, congenital hypothyroidism" in claim 4 and the recitation of "for use in the treatment of disorders due to reduced activity of type I 5'-iodothyronine monodeiodinase" in claim 5 in the preambles are intended use of the compound and as such does not limit the claims. Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F. 3d 801,808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002).

"[T]he recitation of a new intended use for an old product does not make a claim to that old product patentable." In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

The recitation of "having thyromimetic activity" in claim 2 and the recitation of "said reduced activity of type I 5'-iodothyronine monodeiodinase comprises hypothyroidism, non thyroidal systemic illnesses, fast, selenium shortage" in claim 6 in the preambles are merely a new property or function of the composition.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the

applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lopresti et al. ("Characteristics of 3,5,3'-Triiodothyronine Sulfate Metabolism in Euthyroid Man", Journal of Clinical Endocrinology and Metabolism, Vol. 73, No. 4, 1992, pages 703-709, item "CA" on PTO 1449 filed on 02/14/2006) in view of Larsen et al. (US Patent 5,272,078, issue date: Dec. 21, 1993) as applied to claims 8 and 13-15.

Claims 8 and 10-15 are directed to a pharmaceutical composition comprising the compound triiodothyronine sulfate (T_3S). Further limitations include: the amount of T_3S in the composition (claims 10-15), T_3S is formulated in association with thyroxine (claims 8 and 13-15) and the amount of thyroxine in the composition (claims 13-15). Claim 15 limits that the pharmaceutical composition is in a kit.

Lopresti et al. disclose that 25 μCi of 3,5,3'-Triiodothyronine Sulfate (T_3S) in a 5% human albumin solution was administered to human volunteers (page 704, left column, last paragraph). Lopresti et al. disclose that the infusion of 50 μCi of T_3S in a 5% human albumin solution in 500 cc normal saline delivering at 100 cc/hr (page 704, left column, last line, page 704, right column, lines 1-2) was calculated to deliver an estimated serum concentration of 50 ng/DL T_3S followed by 48-hr infusion (page 704, right column, 5th paragraph, lines 4-6). Therefore, Lopresti et al. teach a pharmaceutical composition comprising T_3S.

The difference between Lopresti et al.'s teaching and the instant invention lies in that the prior art fails to teach

(i) the amount of T_3S in the composition (claims 10-15)

(ii) T_3S is formulated in association with thyroxine (claims 8 and13-15)

(ii) the amount of thyroxine in the composition (claims 13-15).

(iv) the pharmaceutical composition is in a kit.

Regarding claims 8 and 13-15 with respect to thyroxine being in the composition of T_3S, Lopresti et al. disclose that T_3S is the preferred substrate for type I deiodinase enzyme system (page 707, right column, lines 6-8). Type I deiodinase catalyzes in the

conversion of thyroxine to triiodothyronine producing the active form of thyroid hormone (Larsen et al., see abstract). Therefore, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to add thyroxine in the composition comprising T_3S to result in the composition of the instant invention as claimed in claims 8 and 13-15 with a reasonable expectation of success. The motivation to do so is to achieve the conversion from thyroxine to triiodothyronine for producing the active form of thyroid hormone (Larsen et al., see abstract).

Regarding claim 15 where the pharmaceutical composition is in a kit, one having ordinary skill in the art would have been motivated at the time the instant invention was made to prepare the pharmaceutical composition as explained above into a kit for it to be used to produce the active form of thyroid hormone in a subject.

Regarding claims 10-15 with respect to the amount of T_3S and the amount of thyroxine in the pharmaceutical composition, the determination of the appropriate dosage amounts of active ingredients for a treatment is routinely made by those of ordinary skill in the art and is well within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information of the active ingredient disclosed in the prior art. Thus, it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to determine the amount of T_3S and the amount of thyroxine for achieving the catalyzing effect of conversion of thyroxine to triiodothyronine to result in the pharmaceutical composition as claimed in claims 10-15 with a reasonable expectation of success.

Applicant's attention is further drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage range is the optimum combination of percentages... Where the general condition of a claim are disclosed in the prior, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BRIAN-YONG S. KWON
PRIMARY EXAMINER

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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NLZ

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